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UNCLAS SECTION 01 OF 03 BRASILIA 000271

SIPDIS

STATE FOR EB/DMALAC, OES/HLEE AND WHA/BSC
STATE PASS EPA FOR JANDERSEN
STATE PASS FOOD AND DRUG ADMINISTRATION FOR RLAKE
STATE PASS USTR FOR SCRININ
USDA FOR U/S JB PENN
USDA FAS FOR ADMINISTRATOR ETERPSTRA
USDA APHIS FOR ADMINISTRATOR BACORD AND BRS/JTURNER
USDA ARS FOR ACTING ADMINISTRATOR EKNIPILING
USDA FAS FOR OA/BSIMMONS
USDOC FOR 4322/ITA/MAC/WH/OLAC/WBASTIAN/TSHIELDS
USAID FOR J/LEWIS

E.O. 12958: N/A

TAGS: [EAGR](#) [ECON](#) [ETRD](#) [TBIO](#) [PGOV](#) [SENV](#) [BR](#) [IPR](#)

SUBJECT: STATUS UPDATE ON BRAZIL'S BIOTECHNOLOGY REGULATIONS

Refs: A) STATE 16321, B) 2003 STATE 263456

1. Post provides the following in response to ref B request.

SUMMARY

2. Biotechnology in Brazil is regulated by the 1995 Biosafety Law 8.974 that established a government commission (CTNBio) to approve genetically modified organisms (GMOs). While the 1995 GMO Biosafety Law remains on the books, regulation of the biotechnology sector in Brazil has remained essentially frozen because of a 1998 court case that is still pending in a federal court in Brasilia filed by environmental NGOs against the use of Monsanto's Roundup Ready soybean variety. This complicated case addresses not only the requirement to conduct environmental impact studies on GMO products, but also the constitutional authority of CTNBio to approve biotech products.

3. In the absence of a definitive court ruling in that case or the passage of the new Biosafety Law, President Lula after taking office on January 1, 2003 issued two Presidential Decrees (both later adopted into law by Congress) that respectively legalized the 2002-03 and 2003-04 biotech soybean crops. On October 31, 2003, President Lula sent to Congress a draft of the long-awaited Biosecurity Law that will provide a long-term regulatory regime for the biotech sector. The text of the bill from the Presidency envisions a complicated mechanism for approval of biotech products by a national biosafety council attached to the Presidency that would consider political and economic, as well as scientific factors. On February 5, 2004, the bill was approved with certain revisions by the Chamber of Deputies and proceeded to the Senate where it is expected to be debated for several weeks. Assessments of the bill as passed vary considerably. Post provides the following information in the interim and will continue to follow and report on the progress of biotech legislation in Brazil. End summary.

Relevant Laws and Regulation

4. Law 8.974 of 1995 - GMO Biosafety Law - Determines the standards for using genetic engineering techniques and the release of genetically-modified organisms into the environment;

Provisional Measure 2191-9 of 2001 - Modifies and creates provisions to Law 8.974/95;

Decree 1.752 of 1995 - Regulates Law 8.974/95;

Law 10.165 of 2000 - Classifies all GMO activities as potentially harmful to the environment, for taxing purposes;

CONAMA Resolution 305 of 2002 - Provides for Licensing and Environmental Impact Study and Report (EIA/RIMA) to GMO enterprises;

Law 7.802 of 1989 - Pesticide Law - Determines registration of biocide products with federal agencies. Given this requirement, any biocide GMOs, such as the BT Corn, shall be registered as pesticides;

Decree 4.680 of 2003 - Regulates Labeling of GMO Food and Food Ingredients.

Specific Rules for Genetically Modified Soybean

5. Law 10.688 of June 13, 2003 (Provisional Measure 113) - Determines the standards for marketing the soybean produced in the 2003 harvest and creates labeling requirements;
Law 10.814 of December 15, 2003 (Provisional Measure 131) -

Determines the standards for planting and marketing genetically modified soybean produced in the 2004 harvest. Makes GM soybean planting and marketing subject to the signature, by the producer, of a TCRAC document (statement of commitment, responsibility and conduct);

Decree 4.846 of September 25, 2003 - Regulates Law 10.814 concerning the TCRAC document;

Law 10.688 (MP 113) of 2003, authorizing the marketing of soybean produced in the 2003 harvest, clearly containing transgenic material, and Law 10.814 (MP 131) of 2003, authorizing producers that had withheld grain from the previous harvest to grow transgenic soybean in 2004 as long as a Statement of Commitment is signed, are of exceptional and non-final character concerning the authorization of GMO commercial production in the country. According to Law 10.814 of 2003, soybean planting for 2005 shall comply with the legislation in force at that time. By converting MP 131 into Law 10.814 of 2003, a provision was created authorizing registration of GM seeds in the National Register of Cultivars of the Ministry of Agriculture (MAPA). Another provision gave amnesty to soybean producers that had failed to comply with the Biosafety Law in the previous harvests.

Bill 2401/2003

16. Designed to replace Law 8.974 of 1995 and permanently regulate GMO activity in the country, including the competency of several government agencies, the President forwarded bill 2401/2003 to the Congress in October. Under this bill, CTNBio is preserved as a joint committee to evaluate GMO-related issues. However, its technical opinion will be binding only when negative. In case of a positive opinion, voting is analyzed (or reviewed) by registration and inspection agencies from MAPA, MS and MMA, within the scope of their competencies. CTNBio would have 26 members, of which 10 scientists and 16 Government and civil society representatives, a restructuring that gives greater weight to non-scientists.

17. The bill creates the National Biosafety Council (CNBS), linked to the Presidency of the Republic, with the responsibility of setting the principles and guidelines for implementing biotech policies as well as making the final decision on approvals of authorization requests concerning GMOs, including marketing and research. This bill already has 278 proposed amendments and will undergo significant modifications, especially concerning the competencies and composition of CTNBio and CNBS. Congress passed the bill with modifications on February 5, 2004, and the bill proceeded to the Senate for further debate.

Monitoring and Enforcement under the 1995 BioSafety Law

18. The regulatory process in place for approving products of agricultural biotechnology for import or sale is laid out in the 1995 Biosafety Law (Law 8974 of January 1995) and the follow-on Presidential Decrees 1752 of 1995 and 2191-9 of 2001. Together, these created a regulatory framework and established CTNBio ("National Technical Commission for Biosafety"), granting it wide authority to evaluate, approve, and regulate GMOs based on scientific criteria for consumer and environmental safety. CTNBio is attached to the Ministry of Science and Technology. There is no blanket legal prohibition on the use, importation or sale of GMOs in Brazil, but no approvals are currently being issued due to the pending court case, with the exception of animal feed products.

19. Under the 1995 law, those wishing to import or sell biotech products must receive approval from CTNBio and authorization to market from one of three regulatory agencies under the Ministry of Health, Agriculture or Environment depending on the nature of the product. Monsanto's Roundup Ready Soy was the first biotech product to receive CTNBio approval in 1998, and the subsequent court case and injunction effectively halted further biotech projects in Brazil. Thus, monitoring and enforcement has never been exercised, as the mandate of the competent authorities (CTNBio) has not been secured. In the interim, only a few Embrapa biotech research projects have been approved through the Ministry of Environment. The Ministry of Agriculture has granted limited approval for biotech products for use as animal feed, such as corn from Argentina for poultry producers in the northeast of Brazil. However, entry of these products has always been obtained through court injunction.

10. No testing system for biotech content of shipments of agricultural products existed under the 1995 law. The GoB is not seriously contemplating a traceability system at this time.

Labeling requirements

11. Executive Order Number 4,680 applies to all biotech products to be marketed in Brazil and establishes, as per article 2, a one-percent limit tolerance level for genetically modified organisms in bulk products, foods and by-products for human or animal consumption. It also allows the CTNBio the prerogative to change the percentage referred in article 2 on a case-by-case basis. The order states that the lack of compliance will entail the penalties foreseen in the Code of Consumer Defense and other applicable rules.

12. For packaged products or those sold in bulk or in natura (raw), the following wording must appear on the front of the label in conjunction with the approved GMO logo (a large black "T" inside of a yellow triangle): "(name of product) transgenic", containing (name of the ingredient or ingredients transgenic (s)) or "product produced with (name of product) transgenic". The order also requires that the consumer be informed of the specie of the donor gene in the place reserved for the identification of the ingredients. All of the label biotech information on the label must also appear on the invoice so that it can follow the product or ingredient in all steps of the productive chain.

13. The food and ingredients produced from animals fed with feed containing transgenic ingredients must have labels printed on the front panel with the following wording: "(name of animal) fed with feed containing transgenic ingredients" or "(name of ingredient) produced from animal fed with feed containing transgenic ingredient."

14. Food and food ingredients that do not contain or are not produced from genetically modified organisms will have earned the right to use the labeling "(name of product or ingredient) free of transgenic" once there are similar transgenic products on the Brazilian market.

15. There are special provisions for products produced from soybeans harvested from the 2003 crop. The labeling requirements go into effect on February 26, 2004.

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